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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,490	01/24/2002	Allan S. Myerson	14960.002USB	4950

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TECHNOPROP COLTON, L.L.C.
P O BOX 567685
ATLANTA, GA 311567685

EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 05/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,490	MYERSON ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2002 and 11 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2002 and 11 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

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1. Applicants' claim for priority set forth at page 1, lines 5-7, is objected to because this application contains new matter with respect to the disclosure of the parent application. For example, the disclosure at page 8, lines 13-17, of the instant specification and of claim 1, step c, is not found in the disclosure of the parent application. The disclosure at page 14, lines 22-24, of the instant specification is changed with respect to the disclosure at page 15, lines 1-3, of the parent application. Accordingly, this application is a continuation-in-part rather than a continuation of parent application 09/694,404. Because of the presence of this new matter in this application, Applicants are not entitled to rely upon a photocopy of the declaration under 37 CFR 1.63 filed in the parent application, and must instead submit a new oath or declaration under 37 CFR 1.63 along with the surcharge under 37 CFR 1.16(e). See MPEP 201.06(c) under "Examination", third paragraph.

The status of parent application 09/694,404 should be updated in any claim for priority submitted in this application.

Correction is required.

2. The disclosure is objected to because of the following informalities: At page 5, line 22, "filed" should be changed to "field". Appropriate correction is required.

3. Claims 1-20 are objected to because of the following informalities: At claim 1, line 9, and claim 11, line 11, "is" should be inserted before "not". Appropriate correction is required.

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The subject matter of claim 1, step (c), is not recited in the instant specification.

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5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,426,406. Although the conflicting claims are not identical, they are not patentably distinct from each other. The '406 patent claims the same method as is recited in the instant claims, except that the '406 patent does not claim growing the polymorph crystal to a desired size, does not claim a laser light wavelength in the near infrared, does not claim laser light in the form of a beam, and does not claim the use of laser light having a high intensity. It would have been obvious to one of ordinary skill in the art to grow polymorph crystals to a desired size in the claimed method of the '406 patent because it is routine in the crystallization art to choose crystallization times and other conditions such that crystals of a desired size are produced. It would have been obvious to one of ordinary skill in the art to determine all operable and optimal laser light wavelengths and intensities in the claimed method of the '406 patent because the '406 patent claims selecting the wavelength, power, and polarization state of the laser light and because it is prima facie obvious to determine and optimize result-effective variables. It would have been obvious to one of ordinary skill in the art to use laser light in the form of a beam in the claimed method of the '406

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patent because a beam is a convenient and typical source of laser light, and because the claimed method of the '406 patent is not limited to any particular source of laser light.

7. Claims 1-12, 19, and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 09/918,935. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '935 application anticipate the instant claims. Because the '935 application claims subjecting the same supersaturated solution of the same substance to the same laser light of the same pulse rate, period, and wavelength and where the supersaturated solution is formed by the same method as is claimed by Applicants, inherently a crystal polymorph will be formed which is different than polymorphs that would nucleate in the absence of the laser light in the claimed method of the '935 application to the same extent claimed by Applicants. Because the '935 application claims selecting the wavelength, power and polarization state of the laser light and claims a pulse rate and period of time, inherently the claimed method of the '935 application will result in growing crystals to a desired size to the same extent claimed by Applicants.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-12, 19, and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of copending Application No. 09/965,751. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '751 application anticipate the instant claims. Because the '751 application claims subjecting the same supersaturated solution

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of the same substance to the same laser light of the same pulse rate, period, and wavelength and where the supersaturated solution is formed by the same method as is claimed by Applicants, inherently a crystal polymorph will be formed which is different than polymorphs that would nucleate in the absence of the laser light in the claimed method of the '751 application to the same extent claimed by Applicants. Because the '751 application claims selecting the wavelength, power and polarization state of the laser light and claims a pulse rate and period of time, inherently the claimed method of the '751 application will result in growing crystals to a desired size to the same extent claimed by Applicants. In any event, the '751 application claims forming seed crystals, which satisfies the instant claim limitation of growing the crystal of the polymorph to a desired size.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. The instant application and copending application 09/918,935 are not currently commonly assigned. Should they eventually become commonly assigned, the following requirement will be made:

Claims 1-12, 19, and 20 will be directed to an invention not patentably distinct from claims 1-33 of commonly assigned 09/918,935. Specifically, see the above provisional obviousness-type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned 09/918,935, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under

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35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

10. The effective filing date of instant claims 11-18 and 20 is deemed to be at least October 23, 2000, the filing date of parent application 09/694,404. Instant claims 11-18 and 20 are deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of the '404 application because the '404 application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed invention.

The effective filing date of instant claims 1-10 and 19 is deemed to be January 24, 2002, the filing date of the instant application. Instant claims 1-10 and 19 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 09/694,404 because the parent application '404, under the test of 35 U.S.C. 112, first paragraph, does not disclose step c of instant claim 1. Accordingly, Myerson (U.S. 2003/0024470), which has a different inventorship than the instant application, is available as prior art against instant claims 1-10 and 19 under 35 U.S.C. 102(e).

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11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-10, 19, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Myerson (U.S. 2003/0024470). Myerson teaches subjecting the same supersaturated solution of the same substance to the same laser light of the same pulse rate, period, and wavelength and where the supersaturated solution is formed by the same method as is claimed by Applicants. See, e.g., claims 1-33 of Myerson. In addition, Myerson teaches growing its protein crystals to a desired size. See, e.g., paragraphs 0020 and 0023. Because the method steps of Myerson are the same as those claimed by Applicants, inherently a crystal polymorph will be formed which is different than polymorphs that would nucleate in the absence of the laser light in the claimed method of the '935 application to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between Myerson and Applicants' claims to shift the burden to Applicants to provide evidence that their claimed invention is unobviously different than Myerson. With respect to instant claims 19 and 20, also note that process limitations do not impart patentability to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art.

13. Claims 11-20 are rejected under 35 U.S.C. 102(b) as being anticipated by the Garetz et al article. The Garetz et al article teaches subjecting a supersaturated aqueous solution of urea

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which have been aged for one to two weeks (168 to 336 hours) to 1.06 μm wavelength, plane-polarized pulses from a Q-switched Nd:YAG laser to induce crystallization of the urea. The supersaturated solution was prepared by first heating and then cooling the urea solution. The power was 0.02 J with the oscillator alone, and 0.1J with the amplifier. The pulse rate was 10 pps, and nucleation typically occurred within 10-20 seconds. Light intensities were 50 and 250 MW/cm^2 (0.05 and .250 GW/cm^2). The laser emits a beam of near infrared light. The solution is transparent to the laser light, i.e. does not absorb the laser light. Needle-shaped crystals are formed, which correspond to the polymorph required to be formed by Applicants' claims. The crystals that initially form tend to be aligned parallel to the electric field vector of the light. See, e.g., the Abstract and page 3475. Urea is an amine. Because the method steps of the Garetz et al article are the same as those recited in the instant claims, inherently the method of the Garetz et al article will also result in a urea polymorph which is different than the urea polymorph that would nucleate in the absence of the wavelength laser light selected by the Garetz et al article. Sufficient evidence of similarity is deemed to be present between the Garetz et al article and Applicants' claims to shift the burden to Applicants to provide evidence that their claimed invention is unobviously different than the Garetz et al article. With respect to instant claims 19 and 20, also note that process limitations do not impart patentability to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art.

14. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by the Garetz et al article as applied against claims 11-20 above, and further in view of the Merck Index. The Merck Index teaches that the urea of the Garetz et al article inherently is a pharmaceutical, e.g. a diuretic, and inherently is a derivative of a protein, i.e. is a product of protein metabolism.

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15. Claim 19 is rejected under 35 U.S.C. 102(b) and claim 20 is rejected under 35 U.S.C. 102(e) as being anticipated by Blanks (U.S. Patent No. 5,976,325). Blanks teaches subjecting a supersaturated aqueous solution of sodium aluminate to about 0.8-4 micron wavelength linearly polarized pulses from a near-IR laser to induce precipitation of alumina hydrate, especially aluminum trihydrate. The supersaturated solution is prepared by the Bayer process and comprises the step of solvent evaporation by flashing. The power can be about 500 to 700 milliwatts. Exemplified treatment times are 15 and 30 minutes. Hexagonal single crystal gibbsite with diameters of typically 15-20 microns are formed, which correspond to the polymorph required to be formed by Applicants' claims, and which are not formed by Bayer processes which do not use the seedless laser treatment. See, e.g., the Abstract; column 1, lines 21-40; column 4, lines 23-28; column 5, lines 36-44; column 6, lines 29-43; column 9, lines 46-48; column 10, lines 22-23; column 11, lines 29-41; column 12, lines 16-17; and the claims. Note that process limitations do not impart patentability to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art.

16. The Garetz et al article is not applied against instant claims 1-10 because the Garetz et al article does not teach or suggest growing crystals of a polymorph to a desired size where the polymorph is different than polymorphs that would nucleate in the absence of the laser light of the Garetz et al article. The Garetz et al article makes no mention of crystal size, nor does the Garetz et al article describe optimizing process parameters which would affect and optimize crystal size.

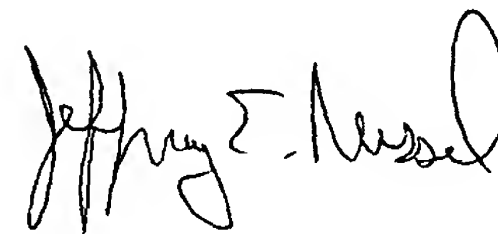
Blanks '325 is not applied against the instant method claims in view of the claim limitations which recite that the solution is not affected chemically by the light. In Blanks '325,

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the laser light chemically destroys undesirable organic compounds which naturally occur in the alumina refining process (see column 6, lines 1-14), and there is no teaching or suggestion that the laser precipitation of Blanks '325 can be made to proceed without the chemical destruction of such organic compounds.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

May 3, 2003